

Notice of Allowability

Application No.

10/659,179

Examiner

Marcela M. Cordero Garcia

Applicant(s)

DEADMAN ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to November 21, 2006.
2. ☒ The allowed claim(s) is/are 1-22,24-26 and 28-94.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the: _____
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 11/21/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

This Office Action is in response to the reply received on November 21, 2005.

Claims 1-21 and 28-40 are pending in the application and have been examined to the extent they read upon the Applicant's elected species. Claims 23, 27 have been cancelled. New claims 41-94 have been added. Claims 22, 24-26 have been rejoined by Examiner (See, Guidance on Treatment of Product and Process Claims in light of in re Ochiai, in re Brouwer and 35 U.S.C. 103(b)," 1184 O.G. (March 26, 1996). Please note that the restriction requirement of June 15, 2005 has been withdrawn.

Any rejection from the previous Office Action, which is not restated here, is withdrawn. The species has been examined and found free of the prior art (see double patenting rejection, below).

Therefore, Examiner has broadened the search to encompass the broad claims 1-22, 24-26 and 28-94.

Claims 1-22, 24-26 and 28-94 have been examined on the merits and found allowable (in view of Examiner's Amendment below).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on November 21, 2005 was filed after the mailing date of the application on September 9, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Double Patenting

The provisional obviousness double patenting rejections [with respect to copending applications 10/659,178 and 11/078,097] as set forth in the previous Office Action are withdrawn without a terminal disclaimer because this is the first application amongst the three applications to be in condition for allowance. (See MPEP 804: "If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.").

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Wayne W. Rupert on February 3, 2006.

The application has been amended as follows:

In Claim 22, at lines 1-3, the phrase "A method of inhibiting thrombin in the prophylaxis or therapy of disease, comprising parenterally administering to a mammal suffering from, or at risk of suffering from," has been omitted and replaced with --A method of inhibiting thrombin comprising parenterally administering to a mammal suffering from--.

In Claims 63-70, at lines 1-3, the phrase "A method of inhibiting thrombin in the prophylaxis or therapy of disease, comprising orally administering to a mammal suffering from, or at risk of suffering from," has been omitted and replaced with --A method of inhibiting thrombin comprising orally administering to a mammal suffering from--.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The prior art does not anticipate or makes obvious the instantly claimed boronic acid multivalent salts and methods of use thereof. The US patent 6,417,174 (cited in the IDS of 11/21/05) teaches organoboronic acids and discloses that calcium, magnesium and aluminum salts may be made thereof (column 9, lines 24), however these boronic acid salts do not contain the moieties instantly claimed, are non-peptidic, do not have the instantly claimed activity and, moreover, are not actually made in any examples. The instant

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application shows that there are unexpected results in terms of compound bioavailability and stability when actually producing the multivalent salts of the instantly claimed boronic acids (see, e.g., disclosure, pages 68-85).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 1-22, 24-26 and 28-94 are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

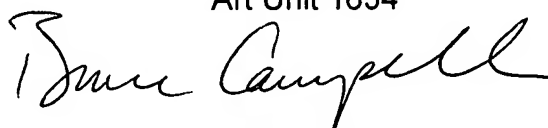
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Patent Examiner
Art Unit 1654

MMCG 02/06


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